PSJ4 SOL Opp Exh 58

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ineffective, or counterfeit drugs.[31] The act prohibits the diversion of prescription drugs or biological products to illegitimate commercial channels or supply chain. It also prohibits the sale of drug samples. The law provides that companies must obtain the signature of a physician for all drug samples. The law requires record-keeping and careful storage of samples.

7. Controlled Substance Act (CSA)[32]

The CSA shows how regulations and compliance impact managing the supply chain. It provides a framework for the federal government to regulate the lawful production, possession, and distribution of controlled substances. The CSA places various plants, drugs, and chemicals (such as narcotics, stimulants, depressants, hallucinogens, and anabolic steroids) into one of five schedules based on the substance's medical use, potential for abuse, and safety or dependence liability. Further, the CSA requires persons who handle controlled substances or listed chemicals (such as drug manufacturers, wholesale distributors, doctors, hospitals, pharmacies, and scientific researchers) to register with the Drug Enforcement Administration (DEA) in the U.S. Department of Justice (DOJ), which administers and enforces the CSA. DEA sets the yearly limit or quota on volume of opioids that can be manufactured. The registrants have to report the sales of opioids to the DEA through the Automation of Reports and Consolidated Orders System (ARCOS) system. The system is not available to any of the registrants who report into the system. This data would have detailed data by registrant that can be helpful to track suspicious orders and limit excessive number of opioid prescriptions.

- Drug manufacturers that design, develop and promote the medication
- Healthcare providers who prescribe the medication
- Wholesalers who distribute the medication
- Pharmacists who dispense the medication
- Private and public health insurance groups that determine what they will pay for
- State medical and pharmacy boards that oversee the doctors and pharmacies in their jurisdiction

Universal access to the ARCOS data would make the system more transparent especially when, for example: a pharmacy is buying from multiple wholesalers or combining its purchases with direct purchasing, which no one wholesaler would be able to determine.

8. Drug Supply Chain Security Act 2013

In addition, in 2013, The Drug Supply Chain Security Act (DSCSA) was enacted requiring the pharmaceutical distribution for prescription drugs be traced throughout the supply chain. By 2023, drug manufacturers, wholesale drug distributors, repackagers, and many dispensers (primarily

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[31] U.S. Food & Drug Administration, *Prescription Drug Marketing Act of 1987*, (March 28, 2018) https://www.fda.gov/regulatoryinformation/lawsenforcedbyfda/significantamendmentstothefdcact/prescriptiondrugmarketingactof1987/default.htm.

[32] United States Drug Enforcement Administration, *The Controlled Substances Act,* https://www.dea.gov/controlled-substances-act (Last Visited on April 12, 2019).